

Practitioner's Docket No. : 39042.0014

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applic. No.: 10/731,375  
Confirm. No.: 4368  
Applicant: Philip J. BARR *et al.*  
Filed: December 8, 2003  
For: METHODS AND COMPOSITIONS FOR TREATMENT OF  
OTITIS MEDIA

Group Art Unit.: 1617  
Examiner: Jennifer M. KIM

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §1.97**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Sir:

Listed below or on an attached Substitute Form PTO-1449 is information known to applicants. A copy is provided of each foreign patent, each publication other than a U.S. patent and U.S. patent application publication, and each cited pending unpublished U.S. application. 37 C.F.R. §§ 1.97-1.98.

Applicants respectfully request that the listed information be considered by the Examiner and be made of record in the above-identified application. If Substitute Form PTO-1449 is enclosed, the Examiner is requested to initial and return it in accordance with MPEP §609.

This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, material to patentability as defined in §1.56.

☐ This statement qualifies under 37 C.F.R. §1.97, subsection (b) because (check all that apply):

- ☐ (1) It is being filed within 3 months of the application filing date and is other than a continued prosecution application under § 1.53(d)  
-- OR --
- ☐ (2) It is being filed within 3 months of entry of a national stage  
-- OR --
- ☐ (3) It is being filed before the mail date of the first Office Action on the merits  
-- OR --
- ☐ (4) It is being filed before the mailing of a first Office Action after the filing of a request for continued examination under § 1.114.

☒ 37 C.F.R. §1.97(c). If this statement is being filed after the latest of: (1) three months beyond the filing date of a national application; (2) three months beyond the date of entry of the national stage as set forth in §1.491 in an international application; or (3) the mailing date of a first Office action on the merits, but before the mailing date of the earlier of a final office action under §1.113 or a notice of allowance under §1.311, then:

- ☐ a certification as specified in §1.97(e) is provided below; **or**
- ☒ a fee of \$180.00 as set forth in §1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this statement.

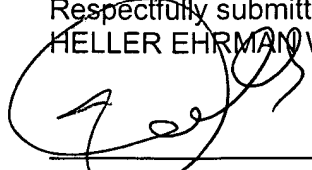
☐ 37 C.F.R. §1.97(d). If this statement is being filed after the mailing date of the earlier of a final office action under §1.113 or a notice of allowance under §1.311, but before payment of the issue fee, then:

- A. a certification as specified in §1.97(e) is completed below; and
- B. a petition under 37 C.F.R. §1.97(d) requesting consideration of this statement is submitted herewith; **and**
- C. a fee of \$130.00 as set forth in §1.17(i)(1) is authorized below, enclosed, or included with the payment of other papers filed together with this statement.

☒ **Fee Authorization.** The Commissioner is hereby authorized to charge the above-referenced fees of **\$ 180.00** and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. **08-1641 (Attorney's Docket No. 39042-0014)**.

Respectfully submitted,  
HELLER EHRMAN WHITE & MCAULIFFE LLP

Date: APR 26 2005

  
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Substitute for form 1449/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

**Complete if Known**

Application Number	10/731,375
Filing Date	December 8, 2003
First Named Inventor	Philip J. BARR
Art Unit	1617
Examiner Name	Jennifer M. KIM
Attorney Docket Number	39042.0014

Sheet

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of

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**U.S. PATENT DOCUMENTS**

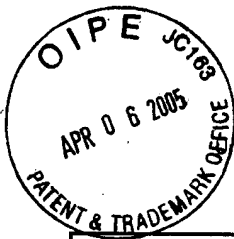
*Examiner Initials	Cite No.	DOCUMENT NUMBER Number - Kind Code (if known) <sup>2</sup>	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	A1	5,780,440	07-14-1998	Lezdey <i>et al.</i>	
	A2	5,532,215	07-02-1996	Lezdey <i>et al.</i>	
	A3	5,492,889	02-20-1996	Lezdey <i>et al.</i>	
	A4	5,346,886	09-13-1994	Lezdey <i>et al.</i>	
	A5	5,215,965	06-01-1993	Lezdey <i>et al.</i>	
	A6	5,190,917	03-02-1993	Lezdey <i>et al.</i>	
	A7	5,166,134	11-24-1992	Lezdey <i>et al.</i>	
	A8	5,134,119	07-28-1992	Lezdey <i>et al.</i>	
	A9	5,093,316	03-03-1992	Lezdey <i>et al.</i>	
	A10	5,679,665	10-21-1997	Bergamini <i>et al.</i>	
	A11	5,631,241	05-20-1997	della Valle <i>et al.</i>	
	A12	5,604,201	02-28-1997	Thomas <i>et al.</i>	
	A13	5,166,331	11-24-1992	Della Valle <i>et al.</i>	
	A14	5,061,729	10-29-1991	Kincses <i>et al.</i>	
	A15	4,474,751	10-02-1984	Haslam <i>et al.</i>	
	A16	4,025,620	05-24-1977	Beyer <i>et al.</i>	
	A17				
	A18				
	A19				

EXAMINER SIGNATURE

DATE CONSIDERED

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Substitute for form 1449/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	10/731,375
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				Art Unit	1617
				Examiner Name	Jennifer M. KIM
Sheet	2	of	2	Attorney Docket Number	39042.0014
<b>OTHER DOCUMENTS - NON-PATENT LITERATURE DOCUMENTS</b>					
Examiner Initials	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published			T <sup>2</sup>
	C1	Reexamination control no. 90/007215: Third Party Request for ex parte reexamination of U.S. Pat. No. 6,174,859			
	C2	Reexamination control no. 90/007215: Order granting reexamination of U.S. Pat. No. 6,174,859			
	C3	Reexamination control no. 90/007215: Patent owner statement under 37 C.F.R. § 1.530			
	C4	Reexamination control no. 90/007215: Third Party Requester Reply under 37 C.F.R. § 1.535			
	C5	ABRAHAM et al., "Mast cells in infection and immunity," <i>Infect. Immun.</i> 65:3501-3508 (1997)			
	C6	AVIDANO et al., "Analysis of protease activity in human otitis media," <i>Otolaryngology - Head and Neck Surgery</i> , 119(4):246 - 351 (October 1998)			
	C7	BAYER CORPORATION. Alpha1-Proteinase Inhibitor (Human). Prolastin®. Revised March 2003.			
	C8	BOYCE, "Mast cells: beyond IgE", <i>J. Allergy Clin. Immunol.</i> 111:24-32 (2003)			
	C9	CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC). "Swimmer's Ear" (Otitis Externa). Fact Sheet for Swimmers. Date unknown.			
	C10	COAN et al., "Preparation and Properties of Alpha1-Proteinase Inhibitor Concentrate from Human Plasma," <i>Vox. Sang.</i> 48:333-342 (1985)			
	C11	FDA, "Electronic Orange Book", excerpts (downloaded 03-16-2005)			
	C12	FORNEY et al., "Anticryptosporidial potential of alpha-1-antitrypsin," <i>J. Eukaryot. Microbiol.</i> 43(5):63S (Sept-Oct 1996)			
	C13	FORNEY et al., "Synergistic anticryptosporidial potential of the combination of alpha-1-antitrypsin and paromomycin," <i>Antimicrobial Agents Chemother.</i> , Sept. 1997, p. 2006 - 2008			
	C14	GALLI et al., "Mast cells to the defense," <i>Nature Immunol.</i> 4:1160-1162 (2003)			
	C15	MATZ et al., "Ototoxicity of ototopical antibiotic drops in humans," <i>Otolaryngol. Head neck Surg.</i> 130:S79-S82 (2004)			
	C16	ROLAND et al., "Animal ototoxicity of topical antibiotics and the relevance to clinical treatment of human subjects," <i>Otolaryngol. Head neck Surg.</i> 130:S57-S78 (2004)			
EXAMINER SIGNATURE				DATE CONSIDERED	